

1765 '99 OCT 15 P2 (15) (16) (16) (16) (16)

September 15, 1999

The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statement:

- (1) Veal bone PMGTM extract supports healthy connective tissue.*
- (2) Manganese is necessary for bone growth, development, and replacement. It is also involved with the health and maintenance of ligaments and tendons.*
- (3) Manganese is an important cofactor of the major enzymes concerned with the formation of muco-polysaccharides and the process of protein metabolism.*

This statement is made for a dietary supplement containing a proprietary blend of veal bone PMGTM extract, calcium lactate, and magnesium citrate. Other ingredients include manganese lactate, honey, and cellulose. The name of the product is Biost®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

an M. Jolden

LET 4423